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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,203	09/22/2006	Yoshinobu Yamazaki	Q96974	5777

23373 7590 12/09/2010  
SUGHRUE MION, PLLC  
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WASHINGTON, DC 20037

EXAMINER
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PAGONAKIS, ANNA

ART UNIT	PAPER NUMBER
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1628

NOTIFICATION DATE	DELIVERY MODE
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12/09/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,203	<b>Applicant(s)</b> YAMAZAKI ET AL.	
	<b>Examiner</b> ANNA PAGONAKIS	<b>Art Unit</b> 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 24 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 15, 16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment filed 11/24/2010 have been received and entered into the present application.

Applicant's arguments filed 11/24/2010 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### **Status of Claims**

Claims 1-12 and 15-18 are currently pending.

Claims 1-10, 15-16 and 18 remain withdrawn.

Claims 11-12 and 17 are currently under examination and the subject matter of the present Office Action.

### **Rejection necessitated by amendment:**

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

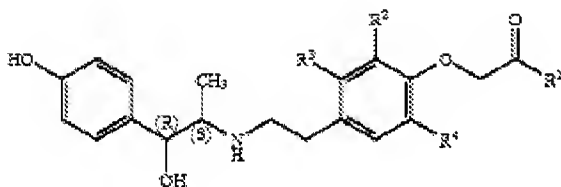
Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner

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to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al (WO 00/02846, cited as a functional language equivalent is U.S. 6,538,152) in view of Garvey et al. (U.S. 2002/0143007) as evidenced by Mesh Supplementary Data (2009; of record) and in further view of Guittard et al. (U.S. 6,262,115) and Sigurdson (U.S. 6,132,365).

Tanaka et al teach the administration of the compound:



where R<sup>2</sup> and R<sup>3</sup> are each lower alkyl groups and pharmaceutically acceptable salts thereof, for the treatment of urinary incontinence (abstract).

Tanaka et al. is silent on the administration of silodosin.

Garvey et al. teaches a method for the treatment of an overactive bladder with the administration of an alpha-adrenergic receptor antagonist such as KMD-3213 (claims 36 and 38). The usual doses of alpha-adrenergic receptor antagonists are about 1 mg to about 100 mg per day, preferably about 0.5 mg to about 10 mg per day (paragraph [0256]).

Mesh Supplementary data teaches that KMD-3213 is an alternative name for silodosin.

Guittard et al. teaches that involuntary urinary incontinence is also known as urge incontinence and overactive bladder (column 1, lines 55-56).

Sigurdson teaches that urinary incontinence is caused by unstable bladder (column 1, lines 34-36).

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references so as to administer silodosin (alpha-

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adrenoreceptor antagonist) in combination with ethyl(-)-2-[4-[2-[[[(1S,2R)-2-hydroxy-2-(4-hydroxyphenyl)-1-ethylethyl]amino]ethyl]-2,5-dimethylphenoxy]acetate in view of teachings of Tanaka et al and Garvey et al. One would have been motivated to do so because each of the therapeutics have been taught in the prior art to be useful for the treatment of urinary incontinence. Further, Guittard et al. teaches that urinary incontinence is alternatively known as an overactive bladder. Additionally, urinary incontinence is known to be associated with unstable bladder, per Sigurdson. Therefore, the idea of combining administration of the two agents flows logically from their having been taught in the prior art. Applying the same logic to the instant claims, one of ordinary skill in the art would have been imbued with a reasonable expectation of success that administration of both agents would be useful for the treatment of urinary incontinence.

With respect to claim 17, the determination of a dosage having the optimum therapeutic index while minimizing adverse and/or unwanted side effects is well within the level of the skilled artisan. The dosage is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would have been obvious for a person of ordinary skill to determine the optimal dosage needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of dosages would have been obvious at the time of Applicant's invention.

### Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 7am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/

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Supervisory Patent Examiner, Art Unit 1628